REINFORCED CATHETER DEVICE, CATHETER STOCK, AND METHODS AND APPARATUS FOR MAKING SAME

Cross-Reference to Related Application

This application is a continuation-in-part of U.S. Application No. 09/715,788, filed November 17, 2000.

Background of the Invention

The subject invention is directed toward the art of vascular catheters and to catheter manufacturing methods and, more particularly, to intravascular microcatheters of unitary construction provided with an integral continuous coiled wire reinforcement member, and to improved methods and apparatus for manufacturing multiples of such catheters from a continuous feedstock.

Angiographic catheters have been widely used for diagnostic purposes such as in conjunction with the injection of dyes or the like into arteries for the visualization of obstructions, ruptures, or other malformations. Diagnostic catheters are typically constructed with an embedded layered wire braid reinforcement system surrounding the lumen to provide torsional control and to strengthen the catheter body to better withstand high pressure injections.

Catheters of the type described above are shown in my prior U.S. Patent No. 3,485,234, which issued December 23, 1969. My prior U.S. Patent No. 3,585,707, which issued June 22, 1971 sets forth generally a method of manufacturing wire braid type angiographic catheters. In addition, my prior U.S. Patent Nos. 5,738,742 and 5,972,143 describe how to manufacture a plurality of

diagnostic catheters having unitary body and tip sections from a continuous feedstock. The teachings of the above prior patents are incorporated herein by reference.

It is likely that wire braid construction will continue to be useful in larger diameter catheters such as in the size range French 8 through French 4. However, in modern medical practice, the use of catheter devices has been broadened to embrace many forms of interventional therapy which require catheters having a smaller diameter. As examples, catheters are presently used in connection with placement of dilation balloons for opening obstructed coronaries and other vessels, for the placement of stints to "prop" open vessels, for introduction of anticoagulants to dissolve clots, and for introduction of coagulants to form clots to "plug" aneurysms or to seal off vessels feeding malignant tumors. The target vessels in the above procedures are typically located in the smaller vessels of the brain, kidney, liver, heart, and other organs. Braided wire catheters, however, are not well suited for applications that require a catheter size of French 3 or smaller. There is a need, therefore, for much smaller catheters that can be extended into the smaller target vessels.

One solution is to construct a catheter that uses a coiled wire reinforcement member within the catheter body as an alternative to the braided wire reinforcement construction scheme. Although the coiled wire construction results in some loss of torsion control, a significantly thinner overall catheter body is enabled. Catheters that include integral coiled wire members have an overall good pushability characteristic and typically do not kink as readily as braided wire construction catheters of the same diameter using the same reinforcement wire diameter.

Another advantage is that coiled reinforcement wire catheters provide a larger lumen size than braided wire type catheters relative to overall catheter body size. Since the reinforcement wire is overlapped in the braided construction as it is braided onto the inner catheter wall construction, the overall reinforcement layer thickness is at least twice as large as in the non-overlapping coiled wire type catheter using the same wire diameter.

U.S. Patent Nos. 5,733,400 and 5,662,622 teach an intravascular catheter carrying a helical reinforcement member embedded within at least a portion of a tubular wall of the catheter. The catheter body is thin and therefore capable of being advanced into small arteries such as in areas of the brain. However, the catheter taught in the above patents is expensive because it is difficult to manufacture. The catheter body is formed from separate sections which are connected end to end.

More particularly, a prior art manufacturing process includes the steps of joining together multiple tubular catheter reinforcement members in end-to-end, abutting relation. For example, a common arrangement is to join four reinforcement members. Next, a UV curable adhesive is placed on the ends of the joined reinforcement members. The ends are covered with a snug, non-adherent transparent sleeve. The adhesive is UV cured and, thereafter, in the cover sleeve is removed.

One major disadvantage of catheters of the type described above is that the manufacturing method is highly time consuming and labor intensive. Further, the overall catheter assembly is susceptible to failure because it is formed of a plurality of individual parts joined end-to-end.

Accordingly, it is therefore desirable to

provide an interventional therapy type catheter having a continuous coil reinforcement member and that is of a substantially unitary construction. Further, it is desirable to provide methods and apparatus for manufacturing multiples of such catheters from a continuous feedstock using a continuous process. In order to reduce manufacturing cycle time, it is desirable to wind the reinforcement wire directly onto an inner substrate layer forming the catheter body in a continuous manner and, thereafter, apply two or more subsequent catheter body layers to produce a large number of catheters from a single feedstock in an efficient manner with minimal labor demands. Individual catheters are simply cut from the feedstock, ground for a selected outer surface finish, and thereafter provided with other finish work as desired.

Summary of the Invention

In accordance with one aspect of the present invention, a reinforced catheter is provided. The reinforced catheter comprises an elongate flexible tubular member defining a lumen of the catheter, the tubular member wall having a first end defining a proximal end of the catheter and a second end defining a distal end of the catheter. A continuous coil reinforcement member is carried on the elongate flexible tubular member and extends between the proximal end of the catheter and the distal end of the catheter. First and second continuous flexible coatings cover the coil reinforcement member and the tubular member in an overlapping fashion substantially entirely between the proximal end of the catheter and the distal end of the catheter. The outer coating is harder than the inner coating and is selectively removed over a length of the catheter to provide a thin flexible tip

portion of the catheter.

In accordance with another aspect of the present invention, a method of manufacturing multiple reinforced catheters is provided. The method includes providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members. A selected length of a reinforcement wire is provided. For substantially the length of the cylindrical tube, the cylindrical tube is advanced from the first spool member to the second spool member while simultaneously reinforcement wire is wrapped onto the portion of the cylindrical tube between the first and second spool members to form a continuous length of reinforced catheter stock. The reinforced catheter stock is then coated with predetermined thicknesses of first and second finish coatings for substantially the length of the cylindrical tube to form a continuous length of coated catheter stock. The coated catheter stock is cut at selected locations corresponding to desired catheter lengths to form a plurality of reinforced catheters. Tip portions of the individual catheters are ground to expose the inner soft finish coating thus forming a flexible tip region.

In accordance with another aspect of the present invention, a reinforced catheter stock for manufacturing reinforced catheters is provided. The catheter stock includes a selected length of an elongate flexible tubular member defining a lumen of the catheter stock, the member having a first end defining a lead end of the catheter stock and a second end defining a trailing end of the catheter stock. A continuous coil reinforcement member is carried on the elongate flexible tubular member and extending between the lead end of the catheter stock and

the trailing end of the catheter stock.

In accordance with another aspect of the present invention, a method of manufacturing a reinforced catheter stock is provided. The method includes the steps of providing a selected length of an elongate cylindrical tube carried on opposite first and second spool members with a portion of the cylindrical tube extending between the first and second spool members. A selected length of a reinforcement wire is provided and, while advancing the cylindrical tube from the first spool member to the second spool member, the reinforcement wire is wrapped onto the cylindrical tube at a point between the first and second spool members for substantially the length of the cylindrical tube to form a continuous length of reinforced catheter stock.

In accordance with another aspect of the present invention, an apparatus for manufacturing reinforced catheter stock is provided. The apparatus includes a first support member and a second support member, the first and second support members being spaced apart and carrying an elongate cylindrical tube with a portion of the cylindrical tube extending between the first support member and the second support member. A winder device carries a selected length of a reinforcement member. The winder device is adapted to wind the reinforcement member onto the cylindrical tube at a point between the first and second support members. A control device simultaneously controls i) advancement of the cylindrical tube relative to the winder device and ii) winding the reinforcement member onto said cylindrical tube by the winder device at the point between the first and second support members.

An object of the invention is a reduction in the cost and time associated with manufacturing intravascular catheters with embedded helical coil reinforcement

members.

Another object of the invention is the provision of an inexpensive intravascular catheter having a unitary construction that is less prone to failure during use. The catheter of the subject invention includes a continuous embedded helical coil reinforcement member that extends between the proximal and distal ends of the catheter body.

Yet another object of the invention is the provision of a reinforced catheter stock for manufacturing multiple reinforced catheters. The reinforced catheter stock includes a continuous embedded helical coil reinforcement member.

A still further object of the invention is the provision of an apparatus for manufacturing intravascular catheters with embedded helical coil reinforcement members from a continuous feedstock.

Still other objects, advantages, and benefits of the invention will become apparent to those skilled in the art upon a reading and understanding of the following detailed description.

Brief Description of the Drawings

The invention may take physical form in certain parts and arrangements of parts, the preferred embodiments of which will be described in detail in this specification and illustrated in the accompanying drawings which form a part hereof, and wherein:

FIGURE 1 is a flow chart showing the preferred method for manufacturing reinforced catheter stock and multiple reinforced catheters from a continuous feedstock in accordance with the present invention;

FIGURES 2a-2f are views in side elevation of catheter stock formed in accordance with the present

invention from a continuous feedstock shown in various stages of sequential construction;

FIGURE 3 is a side elevational view of the coiler tip device for winding the reinforcement wire onto the cylindrical tube as shown in Figs. 2a-2f;

FIGURES 4a-4d are side elevation views of alternate embodiments of individual catheters formed in accordance with the present invention; and,

FIGURE 5 is a diagrammatic view of the preferred apparatus for manufacturing reinforced catheter stock from a continuous feedstock in accordance with the present invention.

Detailed Description of the Preferred Embodiments

Referring now to the drawings wherein the showings are for the purposes of illustrating the preferred embodiments of the invention only and not for purposes of limiting same, Figure 1 shows a flow chart illustrating the preferred method **30** of manufacturing a reinforced catheter. Views showing the preferred catheters of the invention in various stages of sequential construction corresponding to a greater or lesser degree with its manufacturing method **30** are set forth in relative diagrammatic form in Figures 2a-2f and 4a-4d. It will be noted in comparing Figure 1 to the prior art manufacturing process described above that the present invention does not require manual attachment of portions of the catheter in an end-to-end abutting relationship. Rather, the entire sequence of steps involves a progressive processing of what is essentially a single element reinforced catheter.

As shown in Figure 1, the preferred manufacturing method **30** includes the initial step **32** of

providing a selected length of an elongate cylindrical tubular member **50**. A selected length of a reinforcement wire is also provided. Preferably, tubular member **50** (Fig. 2a) is provided carried on a wire mandrel **52** having an outer diameter that corresponds to the desired lumen diameter of the catheter to be made. As an example, for a French 3 size, the nominal lumen diameter is 0.022 inches. The tube **50** could be formed in many ways, but, in the preferred form of the invention, it is formed by extruding a desired thickness of polytetrafluoroethylene (PTFE) material **51**, such as Teflon produced by DuPont, onto a wire mandrel **52** or onto a monofilament mandrel made of a suitable plastic having the desired lumen diameter. In the preferred embodiment illustrated, the mandrel **52** is formed of silver plated copper and is coated with 0.001" thick PTFE material. Essentially, the mandrel **52** provides support as the catheters are built onto the mandrel, but is removed in a final manufacturing step as will be described below.

The wire mandrel used can have substantially any desired length, but is preferably a substantial number of multiples of the desired final length of the catheter bodies being formed. As an example, it is advantageous to construct multiple catheter tube bodies from a continuous reel of 1,000 feet (30.48 m) or more of mandrel feedstock. For catheters having a nominal length of 59 inches (150 cm), the present invention yields over 200 catheters from a single roll of such feedstock.

According to the preferred manufacturing method, the entire length, preferably 1,000 feet (30.48 m) of wire mandrel is passed through a conventional extruder to coat the mandrel **52** with a layer of PTFE material **51** having a desired thickness. Preferably the PTFE layer **51** is about

0.001 inches. However, any thickness may be selected as desired. Thereafter, in a wire wrapping step **38**, the PTFE tube **50** (Fig. 2a), preferably the entire 1,000 foot (30.48 m) length, with the mandrel 52 in place, is passed through an apparatus **100** (Fig. 5) to be described in detail below for overlaying the PTFE tube **50** with a single strand of a small diameter reinforcement wire **54** to form a reinforced catheter stock **60** (Fig. 2d). Preferably, the reinforcement member is a thin stainless steel wire with a preferred diameter of 0.002 inches. It is to be appreciated, of course, that the tube **50** essentially defines the lumen of the finished catheters and forms the inner body portions of the catheter.

In accordance with the preferred method of the invention and with reference to Figures 1 and 5, the wire reinforcement member **54** is wound onto the PTFE tube **50** while the PTFE tube **50** is advanced from a pay-out spool **102** onto a take-up spool **104** in a substantially helical form as shown in Figure 2c. This enables unwrapped portions of the PTFE tube **50** to be held on large spools on a pay-out end **106** of the winding apparatus shown in Figure 5 and further, enables wire wrapped portions of the PTFE tube (i.e., reinforced catheter stock) to be collected in a take-up end **108** of the winding apparatus.

Generally, the apparatus **100** includes the pay-out spool **102** and the take-up spool **104** on opposite pay-out and take-up ends **106, 108** of a frame member **110**, respectively. A pair of guides **112, 114** are supported on the frame member **110** by respective vertical support members **116, 118**, respectively. The first guide **112** is adapted to lead the tube **50** along its path from the pay-out spool **102** to a winder device **120**. The second guide

114 is adapted to route the reinforced catheter stock 60 along its path from the winder device 120 to the take-up spool 104. In that way, the tube 50 upstream of the winder and the reinforced catheter stock 60 downstream of the winder are advanced through the guides 112, 114 while the wire reinforcement member 54 is wrapped thereon in steps 36, 38 shown in Fig. 1.

With continued reference to Figure 5, a winder device 120 is attached at a selected location along a pair of guide beam members 122, 142 of the frame 110. The winder device 120 includes a relatively rigid lower attachment member 124 with a securing mechanism 123 to secure the winder device 120 to the guide beam members 122, 142. Prior to operation, the winder device 120 is slidably moved to a desired position in the horizontal direction shown by the arrows in Figure 5, and thereafter secured on the guide beam members 122, 142 by tightening the securing mechanism 123. The winder device 120 remains secured at the selected horizontal position during winding operations.

The preferred winder device 120 includes an electric winding motor 126 with a rotatable coiler tip member 128 and wire spool 130 on opposite sides of the winder motor 126. A hollow J-tube member 132 is preferably attached to the coiler tip 128 and supported for rotational movement relative to the wire spool 130 and the winding motor 126. The J-tube member in the arrangement of parts illustrated prevents the coiling wire from becoming tangled in the coiler system. Preferably, the winding motor 126 includes a hollow output drive shaft connected to the coiler tip 128 and J-tube member 132 so that the tubular member 50 carried on the mandrel 52 can

be threaded through the winder device **120**.

As best shown in Figures 2c and 3, a lead end **53** of the wire reinforcement member **54** extends through a hollow body portion **125** of the coiler tip **128**, through an offset bore **127** and out from the coiler tip **128** through an offset opening **134**. A substantially central bore **129** extends along the longitudinal axis of the coiler tip **128** and is adapted to receive the catheter body **50** therein in a manner shown in Figs. 2b and 2c. The lead end **53** of the reinforcement member **54** is attached to the lead end of the tube **50** carried on the mandrel **52**. An offset opening **134** is provided in the coiler tip **128** as shown to enable the wire reinforcement member **54** to feed off from the wire spool **130** (Fig. 5) and then successively through the J-tube member **132**, winding motor **126**, and coiler tip **128** substantially as shown. As the winding motor **126** rotates, the wire reinforcement member **54** is payed out from the wire spool **130** and wrapped onto the tubular member **50** while the tube **50** is advanced from the pay-out spool **102** to the take-up spool **104** through the guides **112, 114**.

With reference once again to Figure 1, the preferred method of manufacturing reinforced catheter stock from a continuous feedstock includes the step of advancing the tube **50** carried on the mandrel **52** from the pay-out end **106** of the apparatus **100** toward the take-up end **108**. At step **36**, the tube is advanced from the pay-out spool **102** and wound onto the take-up spool **104**. This presents continuous fresh unwrapped PTFE tube **50** to the winder device **120** from the pay-out spool **102**.

In wrapping step **38**, the wire reinforcement member **54** is wound onto the tube **50** by simultaneously activating the take-up drive motor **144** and the winding

motor **126** using the control device **150**. The control device **150** provides coordinated motion between the winding motor **126** and the take-up drive motor **144** which controls translation of the tubular member **50** carried on the mandrel **52** from the pay-out spool **102** onto the take-up spool **104**.

The advancement of the tube **50** and wrapping the wire reinforcement member **54** onto the tube (steps **36,38**) continues until the entire mandrel coated with tube-forming material is depleted from the pay-out spool **102** at step **40**. At this point **41** in the preferred method, a continuous length of reinforced catheter stock **60** is formed and collected on the take-up spool. Preferably, a nominal length of approximately 1,000 feet (30.48 cm.) of reinforced catheter stock **56** is formed.

In step **42**, the entire length of the reinforced catheter stock **56** (Fig. 2d) is coated with a predetermined thickness of a continuous soft plastic coating **58** to form a continuous length of coated catheter stock **60** (Fig. 2e). In the preferred embodiment, the coating is a soft plastic material having a Shore hardness of about 40D, such as PEBAX available from Elf Atochem.

In step **43**, the entire length of coated catheter stock **60** is coated with a predetermined thickness of a continuous hard plastic coating **62** to form a continuous length of finish coated catheter stock **64** (Fig. 2f). In the preferred embodiment, the finish coating **62** is harder than the base coating **58** and has a shore hardness of about 70D. Preferably, the finish coating is PEBAX available from Elf Atochem.

After the finish coated catheter stock **64** is formed in step **43**, the tube is cut or divided in step **44**

at selected locations to produce individual reinforced catheters **66** (Fig. 4a) having the length and other properties desired. Using this method, each individual reinforced catheter has an inner wall formed by the PTFE material **51**, a wire reinforcement member **54**, an intermediate portion formed by a relatively soft, e.g. 40D, material **58**, and an outer wall portion formed by the relatively hard, e.g. 70D, finish coating **62**.

In the preferred embodiment, the cut catheter lengths are thereafter selectively ground to size and finish at step **46** using a centerless grinding process. Centerless grinders are widely used in industry and in angiographic catheter manufacture in particular. Catheter stock is "fed" though the grinder to remove excess plastic and to bring it to an accurate diameter. The grinder also creates a smooth surface finish. Centerless grinders are also used to grind tapers on catheter tips.

In the centerless grinding step, the part to be ground is rotated under the grinding wheel. The grinding process is preferably accomplished in a manner as described in my earlier U.S. Patent 5,738,742.

The preferred embodiment of the reinforced catheter **68** produced after the grinding step is shown in Figure 4b. The ground end of the reinforced catheter **68** defines a flexible distal portion **72** and an opposite relatively less flexible proximal portion **74**. The distal portion **72** of each catheter **68** is selectively ground to a reduced diameter relative to the proximal portion **74** or main body portion to provide the desired flexibility of the catheter **68** (step **46**). The grinding operation is selectively a one of a step grinding operation or a smooth long taper grinding operation.

An example of the preferred embodiment is a

microcatheter for use in cerebral procedures. In that example, the overall length of the catheter body including the distal portion **72** together with the proximal portion is 155 cm. long. Preferably, the entire length (155 cm.) of the catheter is ground to a nominal outer diameter of 0.033 in. (72.5 mm). Next, the distal portion **72** of the catheter is ground to a diameter of 0.026 in. which becomes the tip segment. The tip segment can be ground to the desired length relative to the proximal portion **74**.

As a preferred example, cerebral microcatheters typically include a soft flexible tip section **72** having an overall length of about 42 cm. It is to be appreciated that a first grinding operation over the length of the catheter essentially forms a catheter body having a substantially uniform cross-sectional dimension. The further grinding step in the distal portion area selectively removes the outer plastic layer **62** leaving exposed the inner more flexible layer **58**. This results in a composite catheter having a soft tip with a harder catheter body.

In another preferred embodiment of the invention, a reinforced catheter **70** (Fig. 4c) with a softer tip portion **76** is provided. First, the finish coating **62** is substantially ground away at the tip portion **76** of the catheter **70** exposing the wire reinforcement member **54** on the PTFE tubular member **50**. Then, a soft plastic compound **78**, for example, Pellethane 55D a urethane product available from Dow Chemical, is fused or molded onto the tip portion **76** of the reinforced catheter **70** (Fig. 4c). The fusing or molding process is preferably accomplished in a manner as described in my earlier U.S. Patent 3,485,234.

Another preferred embodiment includes a

reinforced catheter **80** (Fig. 4d) with one or more marker bands as produced in step **48**. A first marker band **82** is positioned near the distal end of the catheter **80**. The first marker band is secured, preferably by swaging, around the outer surface of the catheter **80**. A second marker band **82** is selectively positioned near the distal end of the catheter **80** and spaced apart from the first marker band **82** by about 3.0 cm. The second marker band is also secured, preferably by swaging, around the outer surface of the catheter **80**. If desired, the marker bands **82** are selectively positioned at other locations and additional marker bands **82** are added to the reinforced catheter **80** as needed.

The invention has been described with reference to the preferred embodiments. Obviously, modifications and alterations will occur to others upon a reading and understanding of this specification. It is intended to include all such modifications and alterations insofar as they come within the scope of the appended claims or the equivalents thereof.